K080075

SECTION 4

JAN 28 2008

SECTION 4 – 510(k) SUMMARY

[As required by 21CFR807.92]

ELITE SURGICAL SUPPLIES (PTY) LTD

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(Please notify via email of correspondence with the Submission correspondent)

SECTION 4

4.1 Date Prepared [21CFR807.92(a)(1)]

November 16, 2007

4.2 Submitter's Information [21CFR807.92(a)(1)]

Company Name:	Elite Surgical US
Street Address:	503 Commerce Park Drive, Suite I
City:	Marietta
State/Province:	Georgia
Country:	USA
Telephone:	404-408-2396
Facsimile:	770-590-5152
Contact Person:	Charise de Barros
Contact Title:	Agent
Contact Email:	Charise@EliteSurgicalUSA.com

4.3 Trade Name, Common Name, Classification [21CFR807.92(a)(2)]

Trade Name:	Vertefix® Pedicle Screw Spinal System
Common Name:	Pedicle Screw Spinal Fixation System
Classification Name:	Spinal Pedicle Screw Fixation Orthosis(MNI) per 21 CFR § 888.3070 Spondylolisthesis Spinal Fixation Orthosis (MNH) per 21 CFR § 888.3070 Spinal Interlaminal Fixation Orthosis (KWP) Per 21 CFR § 888.3050
Device Class:	Class II
Product Code:	MNI, MNH, KWP

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4.4 Identification of Predicate Device(s) [21CFR807.92(a)(3)]

PREDICATE DEVICES
Vertefix Spinal Screw System (K063453)

There are no significant differences between the Vertefix® Pedicle Screw Spinal System and the approved Vertefix® Pedicle Screw Spinal System or other spinal fixation systems currently being marketed, which would adversely affect the use of the product. It is substantially equivalent to these other devices in design, function, materials, operational principles and intended use.

4.5 Description of the Device [21CFR807.92(a)(4)]

The Vertefix® Pedicle Screw Spinal System is a multiple component, posterior spinal fixation system which consists of pedicle screws, rods, set screws, connectors, hooks, and a transverse (cross) linking mechanism.

The Vertefix® Pedicle Screw Spinal System will allow surgeons to build a spinal implant construct to stabilize and promote spinal fusion. The Vertefix® Pedicle Screw Spinal System components are supplied non-sterile, and are single use.

4.6 Intended Use [21CFR807.92(a)(5)]

The Vertefix® Pedicle Screw Spinal System is intended for posterior, non cervical pedicle fixation in skeletally mature patients receiving fusion by autogenous bone graft in the thoracolumbar spine for the following indications: Spondylolisthesis, Trauma (e.g.fracture or dislocation), Spinal stenosis, deformities or curvatures (scoliosis, kyphosis or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

Removal of the implants after the attainment of a solid fusion is optional.

4.7 Technological Characteristics [21CFR807.92(a)(6)]

The original Vertefix® Pedicle Screw Spinal System components were submitted to construct testing according to ASTM F1717.This testing demonstrated substantial equivalence to the predicate systems and other marketed systems. Further comparison to the predicates also demonstrated substantial equivalence in terms of intended use, operating principle, materials, shelf life and design. There are no significant differences between the Vertefix® spinal system, the predicate device,

and other systems currently marketed which would adversely affect the use of the product. The Vertefix® Spinal System components are fabricated from Titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F136. Various sizes of these implants are available for the application. The modified system was not again submitted to the ASTM F1717 testion, as the only significant change to the system is the change to a 5.5mm rod. This will make the system perform slightly better than the already tested Vertefix Spinal System. Thread pullout testing was however performed to prove the thread design.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 28 2008

Elite Surgical Supplies Ltd.
% Elite Surgical US
Ms. Charise De Barros
503 Commerce Park Drive SE, Suite I
Marietta, GA 30060

Re: K080075
Trade/Device Name: Vertefix® Pedicle Screw Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: II
Product Code: MNI, MNH, KWP
Dated: November 16, 2007
Received: January 11, 2008

Dear Ms. De Barros:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 3

INDICATIONS FOR USE

Applicant	**Elite Surgical Supplies (Pty) Ltd**
510(k) Number (if known)	**K080075**
Device Name	**Vertefix® Pedicle Screw Spinal System**

Indications for Use: The Vertefix® Pedicle Screw System is intended for posterior, non-cervical pedicle fixation in skeletally mature patients receiving fusion by autogenous bone graft in the thoracolumbar spine, for the following indications:

- Spondylolisthesis;
- Trauma (e.g. fracture or dislocation);
- Spinal stenosis;
- Deformities or curvatures (scoliosis, kyphosis and lordosis);
- Tumor;
- Pseudoarthrosis; and
- Failed previous fusion.

Prescription Use_____x_____ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080075